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(54) **POWER INJECTION VALVE**

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A61M 3/00 (2006.01)

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See application file for complete search history.

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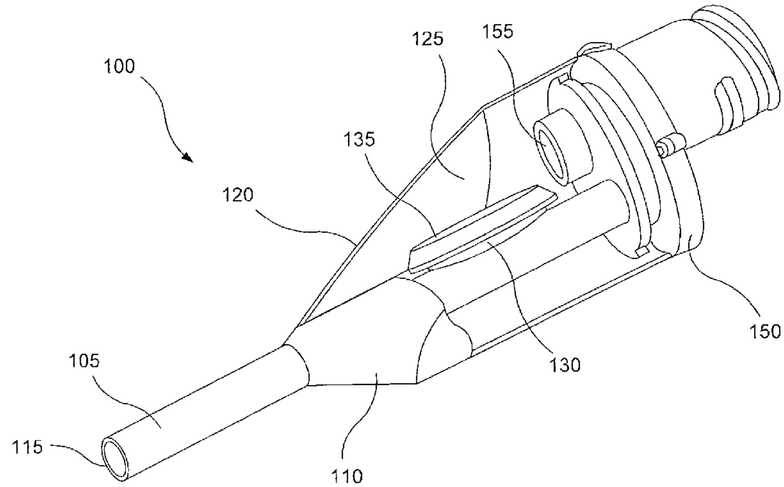
(57) **ABSTRACT**

A device for transferring fluids between an internal structure in a living body and an exterior thereof, comprises a housing including a pressure activated lumen extending to a distal end opening to a power injection lumen that extends to a distal port configured for connection to a fluid conduit extending to a target structure within the body and a pressure activated valve extending across the pressure activated lumen and controlling fluid flow therethrough, the pressure activated valve opening to permit fluid flow therethrough into the power injection lumen when a fluid pressure differential thereacross is at least a first predetermined threshold level and remaining sealed when the fluid pressure differential thereacross is less than the first threshold level in combination with a proximal port coupled to the housing for movement between a first position in which a proximal end of the power injection lumen opens to the proximal port and a second position in which a proximal end of the pressure activated lumen opens to the proximal port.

9 Claims, 4 Drawing Sheets



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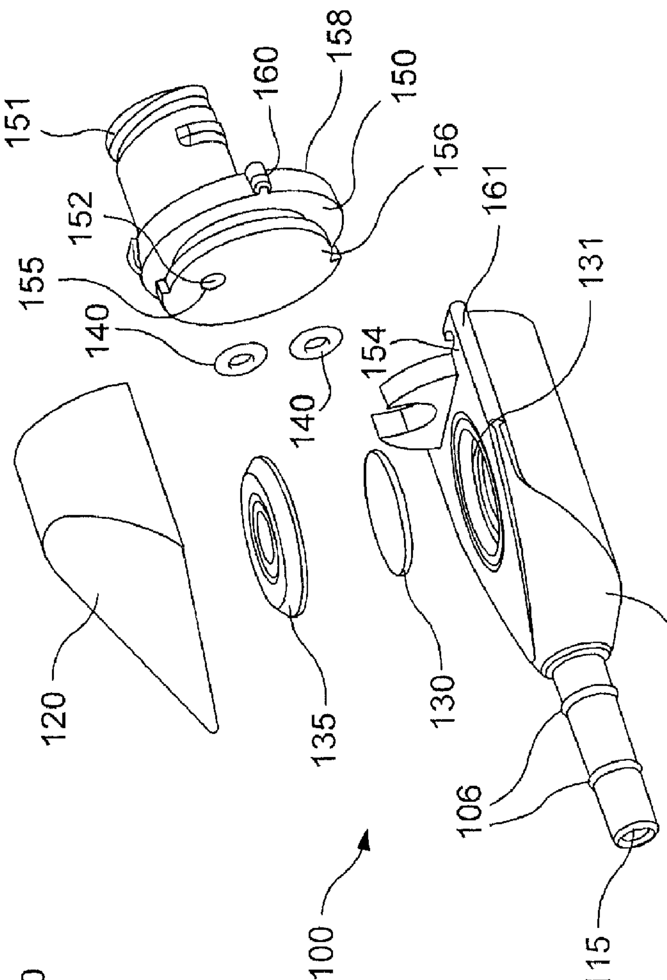
151
160
158
150
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156
155
161
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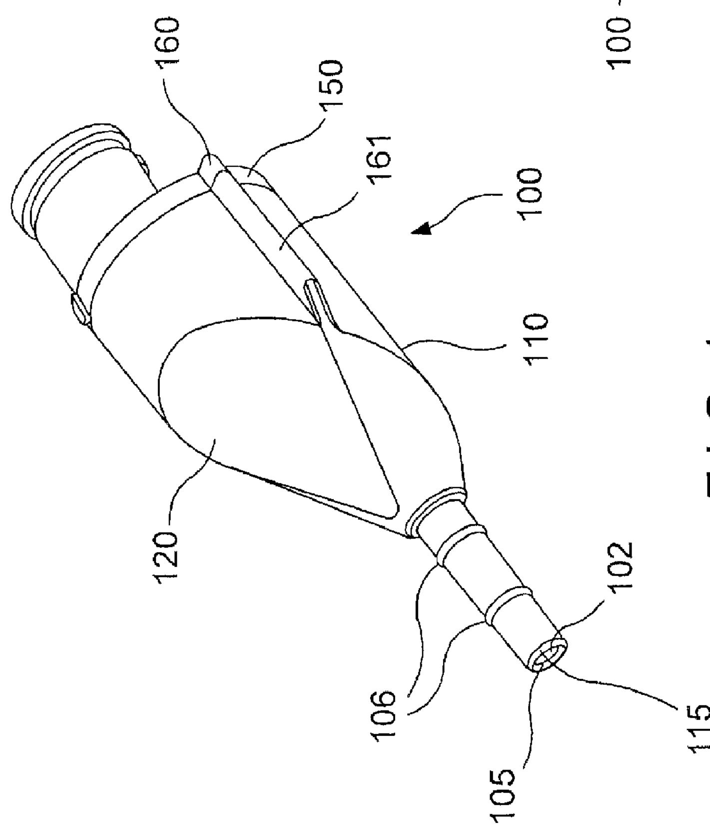
154
140
131
120
135
130
110
106
100
115

F I G. 2


160
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161
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106
115
105

F I G. 1

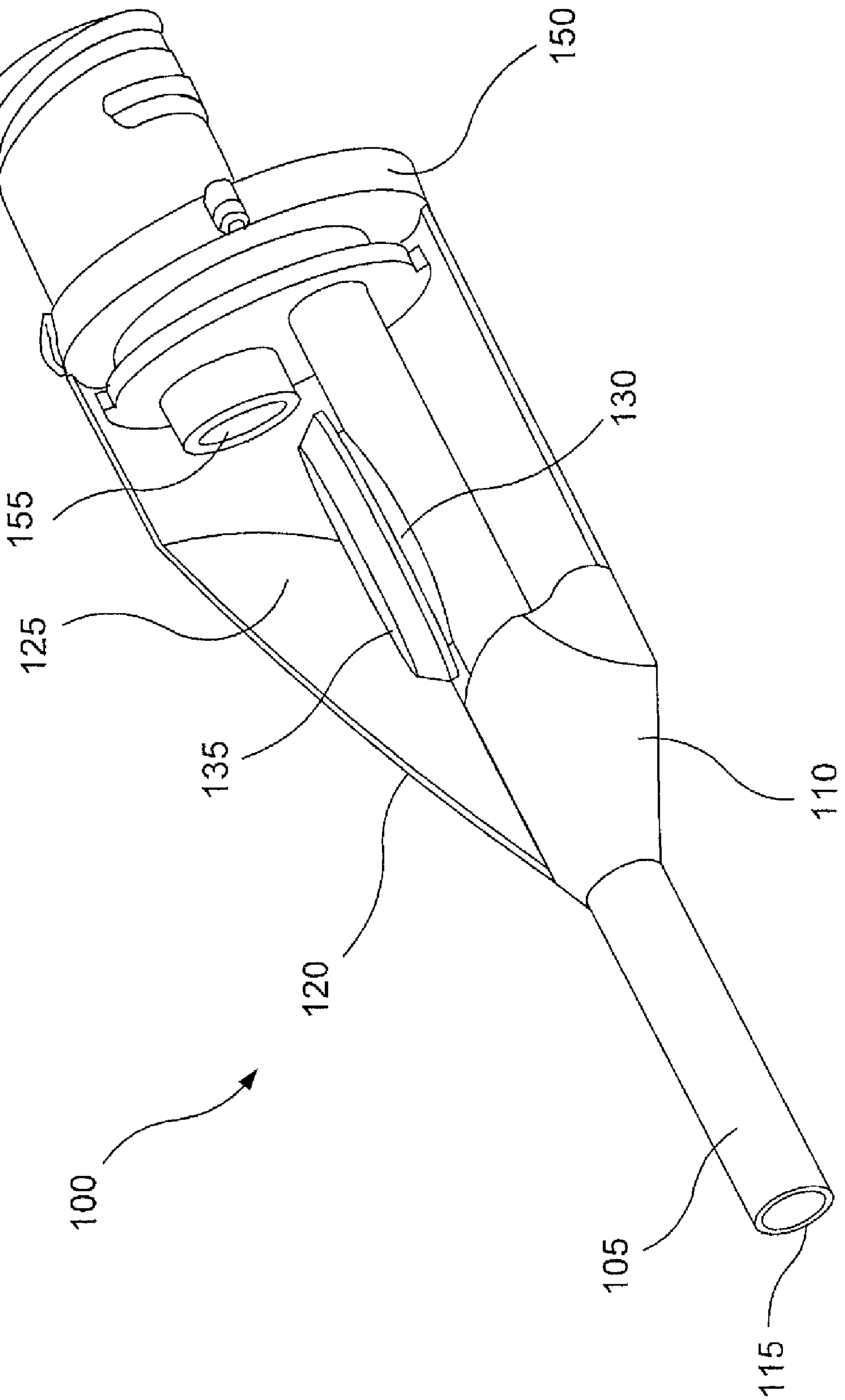

FIG. 3

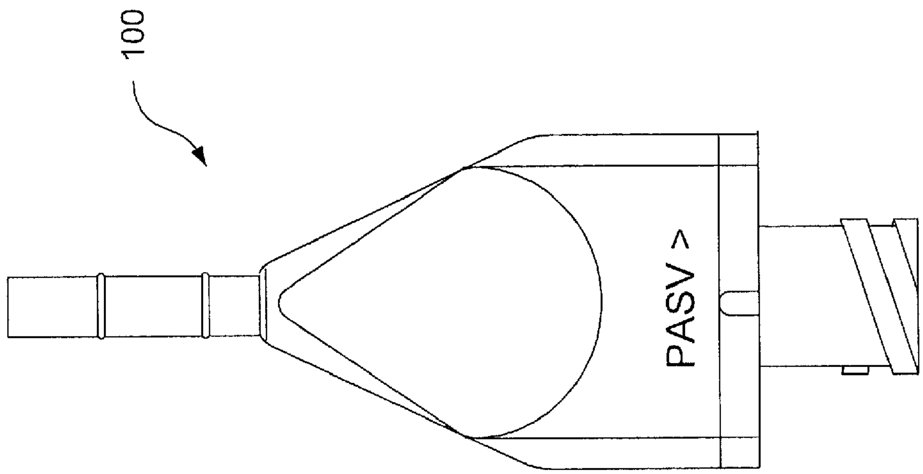

FIG. 6

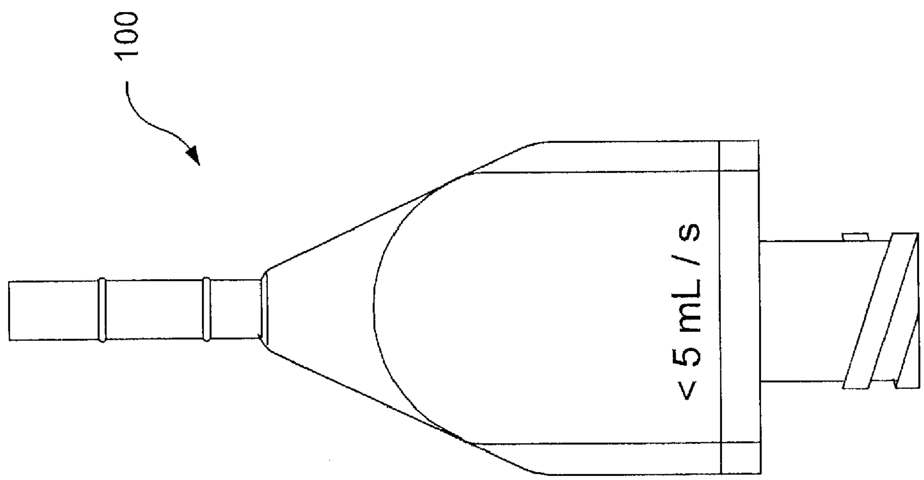

FIG. 5

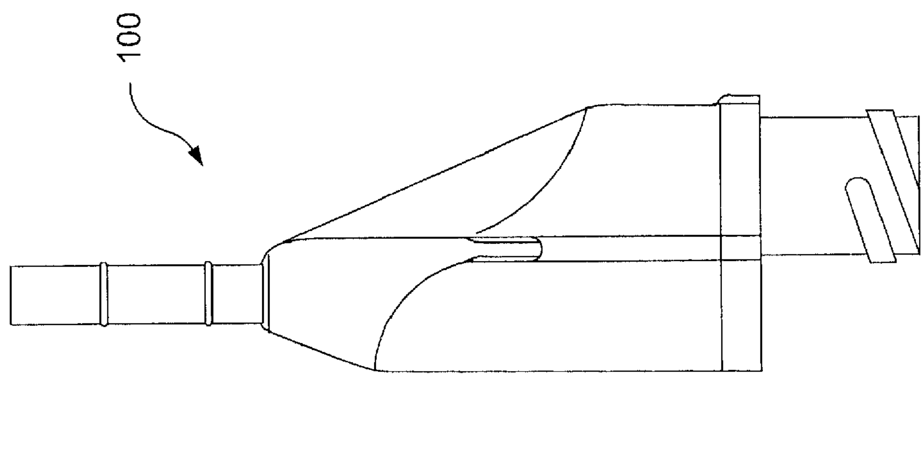

FIG. 4

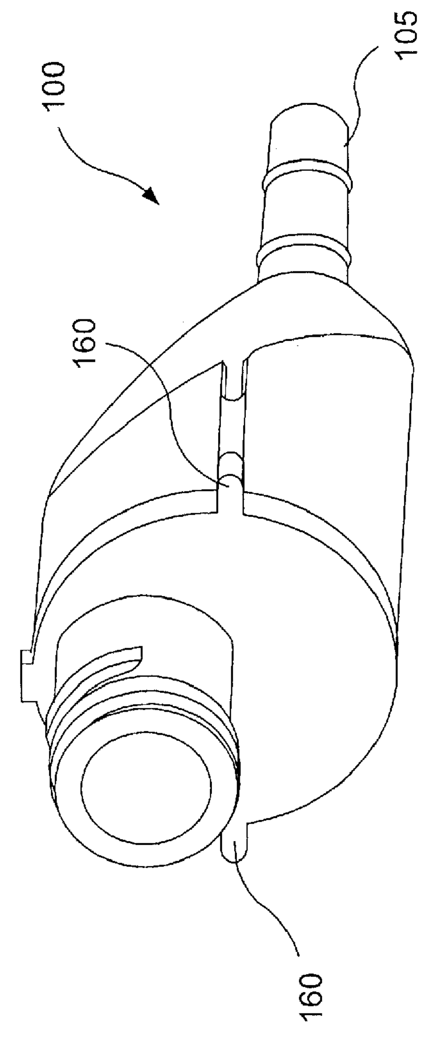

FIG. 7

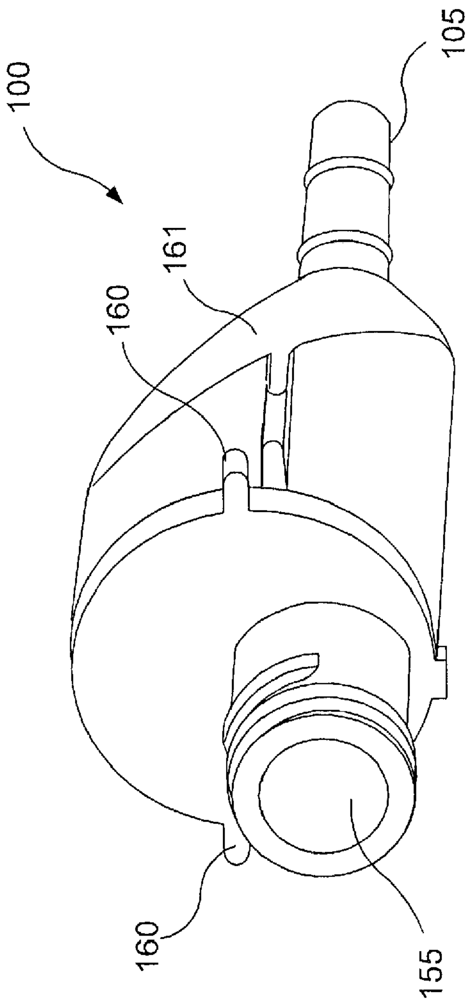

FIG. 8

POWER INJECTION VALVE

BACKGROUND

Procedures requiring the use of peripherally inserted central catheters ("PICC") often employ pressure activated valves to seal these catheters when not in use. Such pressure activated valves are designed to remain closed during normal pressure fluctuations between uses to prevent leakage and backflow which may lead to occlusions and/or infections. However, these valves have often been unsuitable for the injection of fluids at high pressures or volumes.

SUMMARY OF THE INVENTION

The present invention is directed to a device for transferring fluids between an internal structure in a living body and an exterior thereof, comprises a housing including a pressure activated lumen extending to a distal end opening to a power injection lumen that extends to a distal port configured for connection to a fluid conduit extending to a target structure within the body and a pressure activated valve extending across the pressure activated lumen and controlling fluid flow therethrough, the pressure activated valve opening to permit fluid flow therethrough into the power injection lumen when a fluid pressure differential thereacross is at least a first predetermined threshold level and remaining sealed when the fluid pressure differential thereacross is less than the first threshold level in combination with a proximal port coupled to the housing for movement between a first position in which a proximal end of the power injection lumen opens to the proximal port and a second position in which a proximal end of the pressure activated lumen opens to the proximal port.

The present invention is further directed to a method for transferring fluids between a target internal structure of a living body and an exterior of the body, the method comprising connecting to a proximal end of a fluid conduit extending into the body to the target structure a distal port of a housing opening to a power injection lumen thereof, the housing including a pressure activated lumen extending to a distal end opening to the power injection lumen with a pressure activated valve opening to permit fluid flow therethrough into the power injection lumen when a fluid pressure differential thereacross is at least a first predetermined threshold level and remaining sealed when the fluid pressure differential thereacross is less than the first threshold level and moving a proximal port of the housing to a first position in which the proximal port is fluidly coupled to the power injection lumen in combination with supplying a first fluid to the proximal port at a power injection pressure greater than the first threshold level, moving the proximal port of the housing to a first position in which the proximal port is fluidly coupled to the pressure activated lumen and supplying a second fluid to the proximal port at a pressure greater than the first threshold level and less than the power injection pressure.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawing illustrates the design of the present invention wherein:

FIG. **1** shows a first view of an apparatus according to a first embodiment of the present invention;

FIG. **2** shows an exploded view of the device of FIG. **1**;

FIG. **3** shows an internal view of the device of FIG. **1**;

FIG. **4** shows a side view of the device of FIG. **1**;

FIG. **5** shows a bottom view of the device of FIG. **1**;

FIG. **6** shows a top view of the device of FIG. **1**;

FIG. **7** shows a perspective view of the device of FIG. **1** in a position permitting flow through a pressure activated valve; and

FIG. **8** shows a perspective view of the device of FIG. **1** in a normal flow position.

DETAILED DESCRIPTION

The present invention, which may be further understood with reference to the following description and the appended drawings, relates to a system and method for high pressure and high volume injection without damaging a pressure activated valve. In particular, the present invention relates to the selective engagement for high pressure and high volume injection of separate lumens within a device employed in conjunction with a catheter (e.g., a PICC catheter) with at least one of the lumens employing a pressure activated valve.

Presently available pressure activated valves are generally unable to sustain the high pressures and flow rates associated with power injection (e.g., of contrast media). An exemplary embodiment of the present invention seeks to alleviate this problem by incorporating with a pressure activated valve a bypass feature allowing power injection without damaging the pressure activated valve.

As shown in FIGS. **1-8**, a port **100** according to a first embodiment of the invention includes two passages which may be selectively engaged to select either power injection or standard infusion/withdrawal of fluids. The port **100** comprises a base **110** and a cover **120** joined together, for example, via any known means such as bonding, welding, friction fit, etc. Protruding distally from the port **100** is an elongated tubular body **105** with a lumen **115** extending therethrough and into the base **110**, as will be described in greater detail below. It is noted that the term proximal as referred to herein refers to a direction approaching a user or point of user access to the device while distal refers to a direction toward an interior of the body of the patient.

The tubular body **105** is provided with a barbed fitting comprising a series of ridged portions **106** designed to frictionally engage a catheter disposed thereover. Specifically, the ridged portions **106** are formed with a diameter sized to frictionally engage inner walls of a catheter, thereby firmly securing the catheter to the port **100**. Accordingly, to mate to the port **100**, a catheter is guided over the tubular body **105** to a proximal-most position and frictionally retained thereon. In an alternate embodiment, the tubular body **105** may be insert molded on the catheter, as those skilled in the art will understand.

As shown in the exploded view of FIG. **2**, a silicone disk **130** is provided in the port **100**, in engagement with a correspondingly sized recess **131** in the base **110** which opens to the lumen **115**. The silicone disk **130** effectively regulates the pressure and flow of fluids passing therethrough the port **100**. As would be understood by those skilled in the art, the disk **130** may be formed in any desired configuration to obtain desired flow configurations. For example, the disk **130** and a slot or slots therethrough may be formed as shown for any of slitted membranes disclosed in U.S. patent application Ser. No. 10/768,571 entitled "Pressure Activated Safety Valve With Anti-Adherent Coating" filed on Jan. 29, 2004 to Weaver, et al. (the '571 app.); U.S. application Ser. No. 10/768,565 entitled "Pressure Activated Safety Valve With High Flow Slit" filed on even day herewith naming Karla Weaver and Paul DiCarlo as inventors, and U.S. application Ser. No. 10/768,629 entitled "Stacked Membrane For Pressure Actuated Valve" filed on even day herewith naming Karla Weaver and Paul DiCarlo as inventors, and U.S. application

Ser. No. 10/768,855 entitled "Pressure Actuated Safety Valve With Spiral Flow Membrane" filed on even day herewith naming Paul DiCarlo and Karla Weaver as inventors, and U.S. application Ser. No. 10/768,479 entitled "Dual Well Port Device" filed on even day herewith naming Katie Daly, Kristian DiMatteo and Eric Houde as inventors. The entire disclosures of each of these applications are hereby incorporated by reference in this application. The silicone disk **130** is held in place over the recess **131** via a disk retainer **135** which engages a periphery thereof. When the cover **120** is mounted to the base **110**, a portion of the cover **120** engages the disk retainer **135** applying pressure against the disk **130** to hold the disk **130** against a periphery of the recess **131** and prevent the silicone disk **130** from being moved therefrom.

A rotating luer **150** engages a proximal end of the base **110** at a proximal end of the port **100**, as further shown in FIG. **3**. The rotating luer **150** includes a lumen **155** extending therethrough from a proximal end **151** to a distal end **152** and at least two tabs **160** extending therefrom about a circumference of an end plate **158** of the luer **150** which preferably forms a substantially continuous surface with the portion of the port **100** (i.e., proximal ends of the base **110** and the cover **120** regardless of a rotational orientation of the luer **150**. The tabs **160** indicate an alignment of the lumen **155** in relation to the two lumens **115** and **125** of the port **100**, as will be described in greater detail below. The luer **150** also includes a disk-shaped mating projection **156** which is received within a correspondingly shaped and sized slot **154** to rotatably secure the luer **150** to the base **110**.

Two O-rings **140** are provided between the rotating luer **150** and the upper and lower body portions **120**, **110** to provide a fluid seal therebetween. However, those skilled in the art will understand that any number of O-rings may be provided in the device and these O-rings may vary in thickness and size to obtain the desired seal. The O-rings may exhibit elastomeric properties and may, in an exemplary embodiment, be received in recesses formed on a proximal faces of the base **110** and the cover **120** around proximal openings to the lumens **115**, **125**, respectively.

As shown in FIG. **3**, when in a pressure activated position, the lumen **155** of the luer **150** is aligned with the lumen **125** of the cover **120** which opens to the disk **130**. As would be understood by those skilled in the art, when a pressure differential between the lumen **125** and the lumen **115** exceeds a predetermined threshold, edges of the slit(s) in the disk **130** are moved apart from one another and fluid will flow through the disk **130** into the lumen **115** to a catheter attached thereto. When the pressure differential remains below the predetermined threshold, the disk **130** remains sealed preventing fluid flow from the lumen **115** to the lumen **125**.

In order to configure the port **100** in the pressure activated position as also shown in FIGS. **6** and **7**, a user of the port **100** rotates the luer **150** until the tabs **160** are aligned with corresponding projections (e.g., projections **161**) on the port distal body of the port **100** (i.e., the base **110** and/or the cover **120**) to an indicated pressure activated position. Specifically, the proximal portion of the port **100** may be labeled to indicate the locations of the lumens **115** and **125**, as shown in FIGS. **5** and **6**. A physician may then rotate the proximal portion of the port **100** to align the tabs **160** with the projections **161**. Rotating the proximal portion of the port **100** in either a clockwise or counter-clockwise direction until the lumen **155** aligns with the desired lumen of the port **100** engages the desired one of the lumens **125** and **115**. It is further noted that, when the tabs **160** are not aligned with the projections **161**, the port **100** is in an off position with both of the lumens **115** and **125** sealed to prevent the flow of fluid into or out of the proximal portion of the device.

Once the pressure activated valve has been selected, the flow of fluid through the port **100** is guided through the pressure activated valve, as detailed above, with fluid entering the port **100** through an externally attached fluid source via an attachment means shown at the proximal end **151** of the rotating luer **150**. The fluid flows through the lumen **155** and into the lumen **125** and, when the pressure differential exceeds the predetermined threshold level, past the silicone disk **130** into the lumen **115** via the recess **131**. The fluid is passes through the lumen **115** toward the elongated tubular body **105** as flow toward the proximal end of the lumen **115** is prevented by the fluid-tight seal formed by the distal face of the rotating luer **150** which covers the proximal opening to the lumen **115** when the pressure activated valve has been selected. The fluid flows out of the distal opening of the elongated tubular body **105** to a targeted site in the body via a catheter or other device attached to the tubular body portion **105** as would be understood by those skilled in the art.

Alternatively, if the "<5 mL/s" marker is selected, as shown in FIGS. **5** and **8**, the lumen **155** is connected directly to the lumen **115** located inside the base **110** of the port **100**. An external high pressure or high volume fluid source may then be attached to a proximal end of the port **100** so that high pressure and/or high volume fluid (e.g., at flow rates and pressures suitable for the power injection of contrast media) supplied to the port **100** passes directly through the lumen **115** to the distal opening in the body **105** and into the catheter without passing through the disk **130**. It is further noted that the diameter of the lumen **155** may be substantially similar to the diameter of the lumen **115** to allow for an undeterred flow of fluid therethrough.

The present invention has been described with respect to particular designs and embodiments. However, those skilled in the art will understand that the described exemplary embodiments of the present invention may be altered without departing from the spirit or scope of the invention. For example, the port **100** may be altered in geometry, with the diameters of the either of the lumens **115**, **125** and **155** increased or decreased to accommodate the requirements of a patient or procedure for which they are intended. Furthermore, a design may be incorporated with each of the lumens **115** and **125** identified by a different color or pattern of colors, eliminating the need for written markings on the outer body of the port **100**.

It is to be understood that these embodiments have been described in an exemplary manner and are not intended to limit the scope of the invention which is intended to cover all modifications and variations of this invention that come within the scope of the appended claims and their equivalents. The specifications are, therefore, to be regarded in an illustrative rather than a restrictive sense.

What is claimed is:

1. A device for transferring fluids between an internal structure in a living body and an exterior thereof, comprising:

a housing including a pressure activated lumen and a power injection lumen, wherein the power injection lumen extends to a distal port configured for connection to a fluid conduit extending to a target structure within the body;

a pressure activated valve configured to fluidly connect the pressure activated lumen to the power injection lumen and controlling fluid flow therebetween, the pressure activated valve opening to permit fluid flow therethrough into the power injection lumen when a fluid pressure differential thereacross is at least a first predetermined threshold level and remaining sealed when the fluid pressure differential thereacross is less than the first threshold level; and

a proximal port coupled to the housing for movement between a first position in which a proximal end of the power injection lumen opens to the proximal port and a second position in which a proximal end of the pressure activated lumen opens to the proximal port.

2. The device according to claim **1**, wherein, when in the first position, the proximal port seals the proximal end of the pressure activated lumen and, when in the second position, the proximal port seals the proximal end of the pressure injection lumen.

3. The device according to claim **2**, wherein, when in a third position, the proximal port seals the proximal ends of both the pressure activated and power injection lumens.

4. The device according to claim **1**, wherein the pressure activated valve includes a slitted flexible membrane.

5. The device according to claim **4**, wherein the slitted flexible membrane is formed of silicone.

6. The device according to claim **1**, wherein the pressure activated valve opens to permit fluid flow therethrough from the power injection lumen into the pressure activated lumen at a second threshold level higher than the first threshold level.

7. The device according to claim **6**, wherein the pressure activated valve is constructed so that the second threshold level is higher than a pressure differential to which the valve will be subjected during power injection via the power injection lumen.

8. The device according to claim **1**, wherein the proximal port is rotatably coupled to a proximal portion of the housing for rotation between the first and second positions.

9. The device according to claim **1**, wherein the distal port is adapted to couple to a catheter.

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